

# Exhibit A

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel.	)	
ALCHEMY ASSET SERVICES, INC.,	)	
	)	
Plaintiff-Relator,	)	
	)	
v.	)	CIVIL ACTION NO. 10-0680
	)	
GLAXOSMITHKLINE CONSUMER	)	MAGISTRATE JUDGE MITCHELL
HEALTHCARE, LP, and	)	
GLAXOSMITHKLINE, LLC,	)	ELECTRONICALLY FILED
	)	
Defendants.	)	

**BRIEF OF THE UNITED STATES**  
**DEFENDING THE CONSTITUTIONALITY OF 35 U.S.C. § 292**

The United States of America, by its attorneys, David J. Hickton, United States Attorney for the Western District of Pennsylvania, Paul E. Skirtich and Donavan J. Cocas, Assistant United States Attorneys for said District, having exercised its right to intervene to defend the constitutionality of a federal statute under 28 U.S.C. § 2403 and Fed. R. Civ. P. 5.1(c), submits this Brief defending the constitutionality of 35 U.S.C. § 292.

**INTRODUCTION**

On May 18, 2010, Plaintiff Alchemy Asset Services filed a Complaint alleging, among other things, that Defendants GlaxoSmithKline Healthcare, LP, and GlaxoSmithKline, LLC (collectively, "Glaxo") had violated the False Marking Statute, 35 U.S.C. § 292 (hereafter, "Section 292"). See Dkt. No. 1.<sup>1</sup> The *qui*

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<sup>1</sup> Except where otherwise noted, "Dkt. No." shall refer to entries on this Court's docket in the above-captioned matter, and references to "Doc." followed by page numbers shall indicate specific pages in documents filed in this Court.

*tam* provisions of Section 292, which were first enacted in 1842, permit private persons (known as "relators") to file suit under Section 292 for misuse of patent markings.<sup>2</sup> The statute provides for a fine of "not more than \$500 for every such offense," and states that "[a]ny person may sue for the penalty, in which event one-half shall go to the person suing and the other to the use of the United States." See Section 292(a) and (b).

On September 27, 2010, Glaxo filed a Motion to Dismiss the Complaint pursuant to Fed. R. Civ. P. 12(b)(6) and notified the United States Attorney General that it was raising a constitutional question as to a congressional enactment.<sup>3</sup> See Dkt. Nos. 6-8. Among other things, Glaxo argued that Section 292 is facially unconstitutional under the "Take Care" Clause of Article II, § 3 of the United States Constitution because the statute assertedly does not contain an adequate mechanism for Government control of the litigation. See Dkt. 7 at 14-18. Pursuant to an Order of Court, on December 28, 2010, Plaintiff/Relator filed an Amended Complaint. See Dkt. 26. On January 14, 2011, Glaxo then filed another Motion

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<sup>2</sup> The term "*qui tam*" is an abbreviation of the Latin phrase "*qui tam pro domino rege quam pro se ipso*," which means "who pursues this action on our Lord the King's behalf as well as his own." See Vermont Agency of Natural Resources v. United States ex rel. Stevens, 529 U.S. 765, 768 (2000) (citing W. Blackstone, Commentaries on the Laws of England, 160).

<sup>3</sup> To this day, the United States has not been properly served with the Complaint. See Fed. R. Civ. P. 4(i)(1). In filing this Brief, the Government does not waive this (or any other) defect in service.

to Dismiss, again raising the notion that Section 292(b) violates the Take Care clause of the Constitution because the statute fails to give any or adequate control to the Executive Branch of the United States over *qui tam* plaintiffs. See Dkt. 29 at 7-10.

On January 24, 2011, the United States sought permission to intervene under Fed. R. Civ. P. 5.1 for the limited purpose of defending the constitutionality of Section 292(b), which was granted by this Court on January 26, 2011. As a result, the United States files this Brief. For the reasons set forth below, Glaxo's constitutional attack on Section 292(b) must be rejected.

### **ARGUMENT**

A *qui tam* case is an unusual hybrid form of suit having significant characteristics of both a private and a public action. On the one hand, a *qui tam* relator is similar in substantial respects to a plaintiff in a private civil action. The relator does not hold a formal position within the United States Government. Additionally, in his conduct of a *qui tam* case, a relator has a personal financial stake in the suit. On the other hand, a *qui tam* suit properly is regarded as public rather than private litigation inasmuch as the relator files the suit in the name of the United States. Thus, a *qui tam* complaint does not allege that a relator was personally injured by the defendant's unlawful conduct; rather, the gravamen of a *qui tam* suit is an allegation of wrong done to the United States. Because the United

States generally is entitled to substantial recovery in such actions, *qui tam* litigation can benefit the United States financially and can also provide a powerful deterrent to contemplated illegal future conduct.

As the Supreme Court held in Vermont Agency, *qui tam* relators suing under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq., have standing to bring suit in Federal Courts under Article III of the Constitution because they have received a partial assignment of a chose in action by Congress.<sup>4</sup> The Court further explained that "[w]e are confirmed in this conclusion by the long tradition of *qui tam* actions in England and the American Colonies." Vermont Agency, 529 U.S. at 774.

Vermont Agency strongly supports the rejection of an Article II constitutional attack against *qui tam* provisions. Nothing in the Constitution prohibits Congress from using its legislative power to authorize private persons to sue for their own interests and to obtain a recovery that will be shared by a relator and the public Treasury. To the contrary, the long pedigree of *qui tam* actions and the adoption of this mechanism by the earliest federal

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<sup>4</sup> This legislative partial assignment is made pursuant to Congress's power under the Property Clause of the Constitution (Art. IV, Sec. 3, cl. 2), which authorizes Congress to dispose of the interest of the United States in a chose in action. "The power of Congress to dispose of any kind of property belonging to the United States is vested in Congress without limitation." Alabama v. Texas, 347 U.S. 272, 273 (1954).

legislatures and Presidents confirms that *qui tam* provisions, like that set forth in Section 292, are fully consistent with the Framers' conception of the constitutional separation of powers doctrine.

Accordingly, as explained in this Brief, Glaxo's constitutional challenge should be rejected. In Section A, the United States provides a historical overview of *qui tam* legislation and explains how the Supreme Court uniformly has rejected various Article III challenges to the constitutionality of these statutes. Section B analyzes Glaxo's specific Article II "Take Care" Clause challenge to Section 292 and explains why every court to have reached the issue to date has rejected the very same challenge.

**A. THE HISTORY OF THE *QUI TAM* MECHANISM, INCLUDING THAT SET FORTH IN SECTION 292, CONFIRMS ITS CONSTITUTIONALITY.**

The essence of the *qui tam* mechanism is that a private party may bring suit because of a wrong done to the sovereign, and is entitled to a share of the recovery if the action is successful. Blackstone explained that:

T[hese forfeitures created by statute are given at large, to any common informer; or, in other words, to any such person or persons as will sue for the same; and hence such actions are called "popular actions", because they are given to the people in general.

Sometimes one part is given to the king, to the poor, or to some public use, and the other part to the informer or prosecutor. But if anyone hath begun action, no other person can pursue it[.][emphasis added].

J.W. Ehrlich, Ehrlich's Blackstone 545 (1959). Central to any constitutional analysis of *qui tam* provisions is the Supreme Court's observation that "[s]tatutes providing for actions by a common informer, who himself has no interest whatever in the controversy other than that given by statute, have been in existence for hundreds of years in England, and in this country ever since the foundation of our Government." United States ex rel. Marcus v. Hess, 317 U.S. 537, 541 n.4 (1943); accord Marvin v. Trout, 199 U.S. 212, 225 (1905).

In Vermont Agency, the Supreme Court explored the development of the *qui tam* mechanism in England, beginning around the end of the 13th century as a common law device, and soon becoming a standard enforcement mechanism in various statutory schemes. See Vermont Agency, 529 U.S. at 774-76. In a prior decision, C.J. Hendrey Co. v. Moore, 318 U.S. 133, 137-38 (1943), the Court had discussed the development in England of *qui tam* procedures for seizures and forfeitures to the Crown of ships or articles used in violation of the law, whereby a *qui tam* relator brought a civil action and received a share of the forfeiture proceeds. In that opinion, the Court discussed several *qui tam* cases of this type decided by colonial and pre-Constitution courts in America. Id. at 145-48 (citing and discussing Hammond qui tam v. Sloop Carolina, a 1735 case in New York; six other New York *qui tam* cases between

1752 and 1772; and Phile qui tam v. The Ship Anna, a 1788 Pennsylvania case).

By the time the Constitution was adopted, then, statutes authorizing *qui tam* suits had been well-known in England for several hundred years and also had been utilized by the colonial legislatures. See Note, The History and Development of Qui Tam, 1972 Wash. U. L.Q. 81, 83, 94-95. Indeed, the legal careers of colonial attorneys such as Thomas Jefferson included prosecuting *qui tam* actions, and James Madison would have been familiar with these types of cases in Virginia as his older brother retained Thomas Jefferson to handle several. See J. Shestack, Thomas Jefferson: Lawyer (1993), at pp. 18-22.

Based on that history, the Supreme Court in Vermont Agency observed that “[q]ui tam actions appear to have been as prevalent in America as in England, at least in the period immediately before and after the framing of the Constitution.” Id. at 776. As the Court noted, “immediately after the framing, the First Congress enacted a considerable number of informer statutes. Like their English counterparts, some of them provided both a bounty and an express cause of action; others provided a bounty only.” Id. at 776-77 (footnotes omitted).

*Qui tam* actions were a routine feature of early federal legislation. The First Congress enacted several such statutes, and at least five of them hewed closely to the model described by



Blackstone; like Section 292, they set a division of any recovery between the informer and the Government, authorized the informer to file his own suit, and placed no restrictions on the class of persons who could serve as relators.<sup>5</sup> See Vermont Agency, 529 U.S. at 777 n.6 (listing and describing such statutes).<sup>6</sup>

Subsequent early Congresses and Presidents continued to employ this remedial *qui tam* mechanism.<sup>7</sup> See H. Krent, Executive Control

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<sup>5</sup> See Act of Mar. 1, 1790, 2 ch. 2, § 3, 1 Stat. 209 (census); Act of July 5, 1790, ch. 25, § 1, 1 Stat. 129 (extending census provisions to Rhode Island); Act of July 20, 1790, ch. 29, §§ 1, 4, 1 Stat. 131, 133 (regulation of seamen); Act of July 22, 1790, ch. 33, § 3, 1 Stat. 137-138 (trade with Indians); Act of Mar. 3, 1791, ch. 15, § 44, 1 Stat. 209 (duties on liquor).

<sup>6</sup> In addition, under another provision in the Constitution, Congress provided for Federal Court jurisdiction in a manner that is similar to *qui tam* actions. Pursuant to Congress's power to "grant Letters of Marque and Reprisal, and make Rules concerning Captures on Land and Water" (Art. I, Sec. 8, cl. 11), early Congresses authorized the President to commission private ships (privateers) to capture enemy vessels and vessels engaged in illegal trade with enemies. Under the prize statutes, the captor could bring the captured vessel into the jurisdiction of the United States and file an *in rem* action against the ship in Federal Court. If the vessel was condemned, the captor was entitled to the ship or its value. See, e.g., The Sally, 12 U.S. (8 Cranch) 382, 384 (1814) (Story, J.); see also The Nassau, 71 U.S. (4 Wall.) 634, 640-642 (1866). As with *qui tam* provisions, the premise of these prize statutes was that important public purposes could be furthered by encouraging private persons to help enforce the law through the offer of a bounty collected through an action in Federal Court.

<sup>7</sup> See Act of February 20, 1792, ch. 7, § 25, 1 Stat. 239 (2d Cong.; Post Office); see also Act of March 1, 1793, ch. 19, § 12, 1 Stat. 331 (2d Cong.; trading with Indians); Act of May 19, 1796, ch. 30, § 18, 1 Stat. 469, 474 (4th Cong.; trading with Indians); Act of April 2, 1802, ch. 13, § 18, 2 Stat. 139, 145 (7th Cong.; trading with Indians); Act of April 29, 1802, ch. 36,

Over Criminal Law Enforcement: Some Lessons from History, 38 Am. U. L. Rev. 275, 296-300 (1989) (describing early Congressional use of *qui tam* statutes). Indeed, a law enacted by the Second Congress broadly authorized the award of costs in *qui tam* cases. See Act of May 8, 1792, ch. 36, § 5, 1 Stat. 277-78. Thus, by the time of the Second Congress, the *qui tam* mechanism was already regarded as a sufficiently well-established feature of federal law to warrant a general statute governing costs in such suits. This history confirms that *qui tam* suits were a firmly entrenched aspect of American law by the time Section 292 was enacted in 1842, a full 21 years before the False Claims Act (FCA) was enacted.<sup>8</sup> See Act of March 2, 1863. (12 Stat. 696).

The many *qui tam* provisions passed by Congresses and signed by Presidents, as well as their application by the Supreme Court in numerous cases, have created an established practice which

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§§ 3-4, 2 Stat. 171, 172 (7th Cong.; copyright); Act of May 3, 1802, ch. 48, § 4, 2 stat. 189, 191 (7th Cong.; mail carriers).

<sup>8</sup> Besides the FCA and Section 292, Vermont Agency identified three other *qui tam* statutes in existence in 2000 which had been enacted prior to 1900. See 529 U.S. at 768 n.1 (discussing 25 U.S.C. § 201 (penalties for violation of laws protecting commercial interests of Native Americans); 18 U.S.C. § 962 (forfeitures of vessels privately armed against friendly nations); 46 U.S.C. § 723 (forfeiture of vessels taking undersea treasure from the Florida coast)). Additional *qui tam* statutes of more recent vintage remain on the books. See, e.g., 26 U.S.C. § 7341 (forfeiture of sums paid for property sold to avoid tax); see also 17 U.S.C. § 1326 (penalty for false copyright marking).

addresses and answers questions concerning their validity.<sup>9</sup> This is why the Supreme Court has enforced *qui tam* provisions over many decades without raising doubts about their constitutionality. See, e.g., Marvin, 199 U.S. at 225; see also United States ex rel. Marcus, 317 U.S. at 541; United States v. Bornstein, 423 U.S. 303, 309 (1976); Hughes Aircraft Co. v. United States ex rel. Schumer, 520 U.S. 939, 949 (1997).<sup>10</sup> The Supreme Court in Vermont Agency resorted to precisely this type of historical evidence in upholding similar *qui tam* statutes against constitutional attack. See 529 U.S. at 774-78.

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<sup>9</sup> The ways in which constitutional provisions actually have been applied and used during our Nation's history give those provisions definition. See Mistretta v. United States, 488 U.S. 361, 401 (1988) ("traditional ways of conducting government [...] give meaning to the constitution"); The Pocket Veto Case, 279 U.S. 655, 689 (1929) ("long settled and established practice is a consideration of great weight" in constitutional adjudication).

<sup>10</sup> The Supreme Court's decision in United States ex rel. Marcus did not address any constitutional challenges to the *qui tam* mechanism, but it is instructive. In Marcus, the Supreme Court addressed the United States' argument against recovery for a particular *qui tam* relator who had based his suit on the revelations in a criminal indictment. In particular, the Government argued that "effective law enforcement requires that control of litigation be left to the Attorney General." 317 U.S. at 547. The Court rejected that argument because it was "addressed to the wrong forum," but noted that this type of policy argument could be (but had not been) adopted by Congress through amendment of the FCA. The underlying premise of the Court's ruling is that Congress has authority to choose to attack fraud against the United States through *qui tam* provisions if it so desires as a policy matter, and it may determine the terms under which *qui tam* suits may proceed.

Though Vermont Agency was not asked to decide whether *qui tam* suits violate the "Take Care" Clause in Article II, see 529 U.S. at 778 n.8, its analysis cannot be ignored in the context of Glaxo's Article II challenge because the same historical acceptance of *qui tam* provisions that the Supreme Court found conclusive on the issue of Article III standing also establishes the constitutionality of *qui tam* provisions – including Section 292 – under Article II. See Riley v. St. Luke's Episcopal Hosp., 252 F.3d 749, 752 (5th Cir. 2001) (*en banc*) (concluding that the historical analysis in Vermont Agency answered an Article II challenge to *qui tam* provisions under the separation of powers doctrine, explaining: "[I]t is logically inescapable that the same history that was conclusive on the Article III question in [Vermont Agency] with respect to *qui tam* lawsuits initiated under the [FCA] is similarly conclusive with respect to the Article II question concerning this statute.").

As the foregoing indicates, *qui tam* provisions similar or identical to Section 292 were adopted and used on a regular basis by the legislatures and legal systems in England and the American colonies. Early United States Congresses enacted statutes authorizing *qui tam* actions immediately after the adoption of the Constitution. The use of Section 292 in particular by *qui tam* relators has been approved in many reported decisions throughout

the 168 years since its enactment.<sup>11</sup> The long history of *qui tam* statutes in general has been found sufficient to insulate it from Article III challenges, see Vermont Agency, 529 U.S. at 774-78, and there is no reason why that same history should not defeat Article II challenges leveled against Section 292. See Riley, 252 F.3d at 752.

**B. EVERY COURT TO HAVE CONSIDERED THE ISSUE HAS HELD THAT THE *QUI TAM* MECHANISM IN SECTION 292 DOES NOT VIOLATE THE “TAKE CARE” CLAUSE IN ARTICLE II, SECTION 3.**

With the foregoing historical backdrop in mind, the Government now turns to the specific constitutional challenge raised by Glaxo. Succinctly, Glaxo contends that Section 292 violates the “Take Care” Clause because it supposedly “does not give the Executive Branch ‘sufficient control’ over a private citizen’s suit brought on behalf of the United States’ interests.” Doc. 7 at 15; Doc. 29 at 7. This argument has been rejected by every court to have considered it on its merits, and this Court should do the same.

As Glaxo points out, its Article II challenge implicates the separation of powers. See Doc. 7 at 14; Doc. 29 at 7. Though “the

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<sup>11</sup> The earliest reported *qui tam* case under Section 292 appears to be Nichols v. Newell, 18 F. Cas. 199 (C.C.D. Mass. 1853). Subsequent reported decisions demonstrate its continuous use. See, e.g., Winne v. Snow, 19 F. 507 (D. N.Y. 1884); London v. Everett H. Dunbar Corp., 179 F. 506 (1st Cir. 1910); Sippit Cups, Inc. v. Michael’s Creations, Inc., 180 F. Supp. 58 (E.D.N.Y. 1960); Brose v. Sears Roebuck & Co., 455 F.2d 763 (5th Cir. 1972); Forest Group, Inc. v. Bon Tool Co., 590 F.3d 1295 (Fed. Cir. 2009); Stauffer v. Brooks Bros., Inc., 619 F.3d 1321 (Fed. Cir. 2010).

lines between the powers of the three branches are not always neatly defined,” Clinton v. Jones, 520 U.S. 681, 701 (1997), the separation-of-powers doctrine generally prohibits one branch from aggrandizing itself at the expense of another and forbids congressional enactments which “disrupt[] the proper balance between the coordinate branches.” Nixon v. Administrator of Gen. Servs., 433 U.S. 425, 443 (1977). In determining whether a congressional enactment violates separation-of-powers principles, “the proper inquiry focuses on the extent to which it prevents the Executive Branch from accomplishing its constitutionally assigned functions.” Id. Glaxo’s theory is that Section 292 impairs the Executive Branch from accomplishing its “duty to take care that the laws be faithfully executed.” Doc. 7 at 15; Doc. 29 at 9.

To date, every court to have considered “Take Care” Clause challenges to Section 292 have held that the statute does not violate Article II. In Pequignot v. Solo Cup Co., 640 F. Supp.2d 714 (E.D. Va. 2009), aff’d 608 F.3d 1356 (Fed. Cir. 2010), the District Court alluded to some of the history set forth above as a basis for concluding that Section 292 was constitutional, explaining:

[T]he Court finds the long history of *qui tam* statutes, including many passed by the First Congress soon after the signing of the Constitution, see, e.g., 1 Stat. 131, 133, highly persuasive as to their constitutionality. *Qui tam* statutes were part of a long-accepted practice dating back centuries. It is unlikely that the framers would have written a Constitution that outlawed this practice, and then immediately passed several *qui tam*

laws that unconstitutionally encroached on Executive Branch power before the ink on the Constitution was even dry. Of course, passage by the First Congress is not dispositive as to the constitutionality of a law. See Marbury v. Madison, 5 U.S. (1 Cranch) 137, 2 L.Ed. 60 (1803) (striking down provisions of the Judiciary Act of 1789, 1 Stat. 80). However, legislation “passed by the First Congress assembled under the Constitution, many of whose members had taken part in framing that instrument ... is contemporaneous and weighty evidence of its true meaning.” Wisconsin v. Pelican Ins. Co., 127 U.S. 265, 297, 8 S. Ct. 1370, 32 L.Ed. 239 (1888), overruled in part on other grounds by Milwaukee County v. M.E. White Co., 296 U.S. 268, 56 S. Ct. 229, 80 L.Ed. 220 (1935). The long history of *qui tam* actions strongly supports a finding of their constitutionality.

Pequignot, 640 F. Supp.2d at 726. Notably, Glaxo totally ignores the long history of *qui tam* litigation in this country- including the 168-year-long-and-counting history of Section 292 in particular – in its Motion. See Doc. 7 at 14-19; Doc. 29 at 7-10.

Instead, in support of its position that Section 292 violates the “Take Care” Clause,<sup>12</sup> Glaxo seems content to contrast that statute with the FCA, which provides the United States with the right to be notified of a case before the defendant is served; the right to intervene; and, the right to seek dismissal or settlement over the objection of the relator or to prevent dismissal of the action by the relator. See Doc. 7 at 17-18; the same alluded to in

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<sup>12</sup> Glaxo’s specific argument is that Section 292 violates the separation of powers by “vesting another branch’s powers in individuals who, although not controlled by Congress, are not part of the branch authorized by the Constitution to exercise those powers.” See Doc. 7 at 14-15 (*italics omitted*). But none of the three cases cited by Glaxo – and no other case the Government could find – states the standard in that way.

Doc. 29 at 8-9. Glaxo complains that “[t]hese safeguards (or any safeguards) are *entirely* lacking from Section 292.” See Doc. 7 at 17 (footnote omitted; emphasis in original). In Glaxo’s view, the absence of similar provisions from Section 292 can only mean that the Executive Branch lacks “sufficient control” of the conduct of *qui tam* actions brought under that statute, a supposed violation of Morrison v. Olsen, 487 U.S. 654, 696 (1988). See Doc. 7 at 15; Doc. 29 at 9.

To understand why Glaxo’s Article II challenge is meritless, a brief look at Morrison is necessary because it is the source of the “sufficient control” standard. In that case, the Supreme Court rejected an Article II challenge to a law establishing an independent counsel to investigate wrongdoing by certain Executive Branch officials. In upholding the statute’s constitutionality, the Court held that the statute provided the Executive with “sufficient control ... to ensure that the President is able to perform his constitutionally assigned duties.” Morrison, 487 U.S. at 696. In particular, Morrison found that the Executive Branch retained the power to appoint the independent counsel as well as to remove him or her for good cause, to define the independent counsel’s jurisdiction, and to set Justice Department policies by which the independent counsel had to abide. See id.

Any suggestion that Morrison applies to Section 292 was put to rest in Pequignot. For in Pequignot, the defendant challenged the



constitutionality of Section 292 on the ground that it violated the "Take Care" Clause because it did not afford "sufficient control" under Morrison, just as Glaxo does here. See 640 F. Supp.2d at 726. The court's carefully-reasoned rejection of that argument is worth quoting at length:

[I]t is not necessary for § 292(b) to meet the demanding standard applied by the Supreme Court in Morrison to withstand an Article II challenge, given that the intrusion of § 292(b) into Executive Branch power is minor in comparison. See Riley, 252 F.3d at 755 (holding that "the Morrison control test ... is simply not dispositive of [a challenge to the FCA], as it involves an entirely different lawsuit and requires entirely different control mechanisms."). **A *qui tam* relator under § 292(b) pursues a civil action, not a criminal one. Because civil actions do not "cut [] to the heart of the Executive's constitutional duty to take care that the laws are faithfully executed," the Executive Branch need not wield the same level of control over civil litigation as over criminal prosecutions. See Riley, 252 F.3d at 755. This principle is particularly compelling in the area of patent law, where private parties routinely litigate matters concerning the validity, enforceability, and infringement of patents. Quite simply, enforcement of the substantive provisions of § 292 is not the type of executive function whose delegation to an authority not controlled by the Executive Branch would presumptively raise serious Article II questions.** Moreover, the actual power wielded by a relator under § 292(b) pales in comparison to that granted to the independent prosecutor in Morrison. The independent counsel was given "full power and independent authority to exercise all investigative and prosecutorial functions and powers of the Department of Justice." Morrison, 487 U.S. at 662, 108 S. Ct. 2597. In stark contrast, a *qui tam* relator under § 292(b) can maintain only one type of suit – an action for false patent marking – and must do so at his own expense. Finally, § 292(b) does not bar the government from initiating its own action, criminal or civil, to enforce the substantive false marking provisions of §292(a). By comparison, in Morrison, once a matter was referred to an independent counsel, the

Attorney General and Justice Department were required to suspend all investigations and proceedings regarding that matter. See id. at 662-63, 108 S. Ct. 2597. For all of the above reasons, the Court concludes, as applied to the enforcement of proper use of patent markings, that the constitutional mandate that the Executive Branch "take care that the laws be faithfully executed" can be satisfied with a significantly lesser degree of control than the Supreme Court required in Morrison. [emphasis added].

Pequignot, 640 F. Supp.2d at 726-27 (footnote omitted). The United States agrees that Morrison is inapplicable to Section 292 for the reasons stated in Pequignot.

Pequignot next rejected the defendant's argument that the Executive Branch has no control of suits initiated by relators under Section 292, the same argument that Glaxo makes in absolutist terms here. See Doc. 7 at 18; Doc. 29 at 9. In Pequignot, the court explained:

[D]espite the lack of control mechanisms in § 292(b) itself, the Executive Branch is not without the ability to assert its interests in a § 292(b) *qui tam* action. The clerks of federal courts are required to notify the Director of the United States Patent and Trademark Office of any patent suits within one month of their filing. See 35 U.S.C. § 290. The United States may intervene in a *qui tam* action, either as of right, see Fed. R. Civ. P. 24(a)(2), or with a court's permission, see Fed. R. Civ. P. 24(b). If the United States intervenes and the *qui tam* relator attempts to voluntarily dismiss the case, it cannot do so without a court order if the United States does not consent. See Fed. R. Civ. P. 41(a)(1)(A)(ii) (allowing dismissal without a court order only if "all parties who have appeared" sign a stipulation of dismissal). Finally, the United States may apply for a protective order if the relator's action interferes with a government investigation or prosecution. See Fed. R. Civ. P. 26(c).

See Pequignot, 640 F. Supp.2d at 727-28. The District Court concluded: "Although these mechanisms concededly do not rise to the same level of government control provided by the FCA, the FCA's strict safeguards are not required because [...] § 292(b) represents a minimal intrusion onto Executive Branch power." Id. at 728. The only two (2) other courts to have addressed this issue to date have agreed.<sup>13</sup> These cases correctly have concluded that the Executive Branch retains sufficient control of relator litigation under Section 292 for that statute to pass Article II muster.

Finally, though Glaxo insists that this purported "lack of control is not merely a theoretical problem," it then proceeds to describe hypothetical situations which could, in its view, create Article II concerns should they ever materialize. See Doc. 7 at 18; Doc. 29 at 9. Pequignot rejected a similar attempt by the defendant in that case, explaining:

Although [the defendant] has raised concerns regarding separation-of-powers issues that might arise if the government desired to litigate a § 292(b) action in a

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<sup>13</sup> See Shizzle Pop, LLC v. Wham-O, Inc., No. 10-cv-3491, 2010 WL 3063066, at \*3 (C.D. Cal. Aug. 2, 2010) (echoing Pequignot's observation that there were ample mechanisms through which the United States could control *qui tam* actions brought by relators via Section 292); see also Harrington v. CIBA Vision Corp., No. 08-cv-251 (W.D.N.C.) (transcript of oral decision denying motion to dismiss Section 292 on the ground that it violated the "Take Care" Clause and holding that the statute **did** give the Executive Branch "sufficient control," even under the more demanding Morrison standard) (excerpts attached hereto as Exhibit A).

different manner than the *qui tam* relator, the Court need not decide whether such a fact pattern would pose constitutional problems, because that is not the case here. Although the United States has not intervened as a full and active participant in the litigation, it has intervened to defend the constitutionality of § 292(b) and Pequignot's ability to sue [the defendant]. That the Executive Branch, the very entity [the defendant] alleges has been "impermissibly undermined," has intervened and expressed no objection to the manner in which Pequignot has prosecuted his suit – and has actually supported Pequignot's action in all respects – is additional persuasive evidence that separation-of-powers principles have not been violated here.

Pequignot, 640 F. Supp.2d at 728 (citation, internal quotation marks, and footnote omitted). The court concluded that "[i]t is unnecessary to decide whether, on different facts, Article II might be violated." Id. Pequignot is correct on this point, and even if this issue were in doubt, this Court still could construe the other relevant statutory and procedural provisions cited in Pequignot to allow the United States to achieve its objectives without reaching any constitutional question, should the United States decide to intervene on the merits in the future. See id. at 727-28. But as things stand today, it is neither necessary nor appropriate for the Court to resolve the hypothetical constitutional issues that Glaxo raises. See Public Citizen v. United States Dep't of Justice, 491 U.S. 440, 465-66 (1989).

In the end, Glaxo's "Take Care" Clause challenge to Section 292 has been addressed and rejected by the holding in Pequignot and – in less formal fashion – by those in Harrington and Shizzle Pop. Notably, Glaxo cites none of these cases. See Doc. 7 at 14-18.;

Doc. 26 at 7-10. Moreover, the “sufficient control” standard articulated in Morrison does not apply but, even if it did, nothing in Section 292 so bereaves the Executive Branch of control in relator-initiated *qui tam* litigation that the Executive is prevented from accomplishing any constitutionally-assigned functions, including its duty to “take care” that the laws be enforced. Finally, the only ripe constitutional question is whether, consistent with Article II, a private party may initiate a *qui tam* action under Section 292 without Executive Branch involvement. Because nothing in Article II categorically forecloses that result, Section 292 is not unconstitutional.

### CONCLUSION

For all of the foregoing reasons, Glaxo's assertion that Section 292 violates the "Take Care" Clause of Article II must be rejected.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of January, 2011, a true and correct copy of the within Brief of the United States Defending the Constitutionality of 35 U.S.C. § 292 was electronically filed and/or served by postage-paid U.S. Mail, to and upon the following:

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